

REMARKS

The Specification was objected to for use of the trademark ATCC, and lack of ATCC Accession numbers. The title was objected to for use of the work novel.

The Specification and the Title have been amended to address the objections, thus rendering the objections moot. Withdrawal of the objections is respectfully requested.

Claims 23-32 were rejected under 35 USC 101 for lack of a specific and substantial asserted utility or a well established utility. The rejection is traversed.

Applicant's respectfully assert that in fact a *specific* and *substantial* utility is *asserted* in the present application for use of the claimed nucleic acids. Applicants have asserted at least that the presently claimed compositions are useful in the identification of compounds which modulate LGR6 in an attempt to identify candidate compounds for treatment of LGR6 related disorders. The relative disorders are specific, as Applicants have set forth use of identified compounds in, metabolic (e.g., weight disorders), cardiovascular, or CNS disorders. The identified utility is specific, and the use is based on Applicants identification of regulated expression. See, e.g., page 27, lines 8-10, lines 22-30, page 86, line 5 through page 93 line 8. For example, LGR6 expression is regulated in developing mouse and demonstrates expression in fat and hypothalamic tissues (tissues known to be involved in regulation of metabolic disorders). See page 27 line 31 through page 28 line 6 and Example 2.

According to the Utility Guidelines issued, a specific utility is met, for example, when a method for identifying compounds which modulate a receptor is asserted. See Utility Guidelines Training Materials, Example 12. Further, a substantial utility is met, for example, when a specific disclosed disease or condition for treatment using the identified compound is asserted. See Utility Guidelines Training Materials, Example 12. Here, in contrast to the referenced example, specific disorder is in fact identified.

Applicants respectfully submit the specific substantial utility asserted is a credible utility. Further, Applicants submit the Examiner has not met the requirement for an effective rebuttal of the asserted utility under the Utility Guidelines Training Materials. Under the Guidelines:

*An assertion is credible unless*

*(A) the logic underlying the assertion is seriously flawed, or (B) the facts upon which the assertion is based are inconsistent with the logic underlying the assertion. Credibility as used in this context refers to the reliability of the statement based on the logic and facts that are offered by the applicant to support the assertion of utility. A credible utility is assessed from the standpoint of whether a person of ordinary skill in the art would accept that the recited or disclosed invention is currently available for such use. See Utility Guidelines Training Materials page 3.*

Where a specific and substantial utility is set forth, the Examiner must provide a prima facie showing of lack of credibility. According to the Utility Guidelines as set forth in the MPEP:

*Where the asserted specific and substantial utility is not credible, a prima facie showing of no specific and substantial credible utility must establish that it is more likely than not that a person skilled in the art would not consider credible any specific and substantial utility asserted by the applicant for the claimed invention. The prima facie showing must contain the following elements:*

- (i) An explanation that clearly sets forth the reasoning used in concluding that the asserted specific and substantial utility is not credible;*
- (ii) Support for factual findings relied upon in reaching this conclusion; and*
- (iii) An evaluation of all relevant evidence of record, including utilities taught in the closest prior art.*

See MPEP 2107.

Applicants respectfully submit the Examiner has not met the requirement to establish a prima facie showing that one of skill in the art would not consider credible the asserted specific and substantial utility asserted in the present application (e.g., use for identification of diagnostics and/or therapeutics in metabolic disorders, eg, weight disorders). In order to make such a showing, the Examiner must provide a clear explanation refuting such utility as well as factual findings to support such conclusions.

In view of the foregoing, Applicants respectfully submit the rejection under 35 USC 101 is improper. Reconsideration and withdrawal of the rejection is requested.

Claims 23-32 were also rejected under 35 USC 112, first paragraph because the claimed invention purportedly lacks utility. The rejection is traversed.

As described above, the LGR6 molecules of the present invention are in fact supported by a specific and substantial asserted utility. Withdrawal of the rejection is thus respectfully requested.

Claim 23 was rejected under 35 USC 112, first paragraph for lack of written description, because of the overly broad limitation of "at least about 90% identical." The rejection is traversed.

Claim 23 was also rejected under 35 USC 112, second paragraph for failing to particularly point out and distinctly claim the subject matter of the invention, for use of the term "about 90% identical." The rejection is traversed.

Applicants have amended claim 23 so as to eliminate "about." It is believed the amendments contained herein renders the rejection moot. Withdrawal of the rejections is thus requested.

This paper is being filed timely as a request for a one month extension of time is filed concurrently herewith. No additional extensions of time are required. In the event any additional extensions of time are necessary, the undersigned hereby authorizes the requisite fees to be charged to Deposit Account No. 501668.

Entry of the remarks made herein is respectfully requested.

26 March 2003

Respectfully submitted,

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